DRUG MANUFACTURING LICENSE APPLICATION

INSTRUCTIONS: A separate application <u>SUBMITTED IN DUPLICATE</u> is required for each place of business. Please complete and/or amend this application as appropriate.

The fee for each RENEWAL or NEW application in the sum indicated per fee schedule below payable to the STATE DEPARTMENT OF HEALTH SERVICES must accompany this application. The penalty for failure to apply for renewal within 30 days after expiration is \$10.00 and must be added to the renewal fee before the license may be issued. Unsigned or incomplete applications cannot be processed. Please submit original and duplicate applications with fee and penalty if applicable to:

DEPARTMENT OF HEALTH SERVICES LICENSE NO.: FOOD AND DRUG BRANCH EXPIRATION DATE: P.O. BOX 942832 FEE: \$402.31 **SACRAMENTO, CA 94234-0006** MAIL DATE: 916/445-2263 DISTRICT: NAME OF FIRM AND DBA(S) IF APPROPRIATE: FDA REGISTRATION NUMBER: TYPE OF APPLICATION: RENEWAL () NEW () LOCATION OF FIRM: (Street, City, Zip, Phone) CORRESPONDENCE ADDRESS: (PO Box, City, State, Zip, Phone) Area Code/Phone Area Code/Phone PERSON RESPONSIBLE FOR MANUFACTURE AT THIS PLACE: PERSON RESPONSIBLE FOR ALL CORRESPONDENCE: NAME(S) AND TITLE(S) OF OWNER(S) OR CORPORATE OFFICERS. IF A SUBSIDIARY, NAME AND ADDRESS OF PARENT FIRM: CODES OF PRODUCTS TO BE MANUFACTURED: CODES OF PROCESSING TO BE UTILIZED: SELECT BY PLACING AN X IN THE BRACKETS DELETE BY DRAWING A LINE THROUGH THE X [] 708 Biologics [] 700 Over-The-Counter [] AER Aerosolization [] PMX Powder Mixing [] 709 Parenteral [] REL Relabel Only [] 701 Prescription (Rx) [] ASP Aseptic [] 702 Radioactive [] 710 Bulk Pharmaceutical [] COT Coating [] REP Repackage Only [] EML Emulsification [] STR Sterilization [] 703 Veterinary [] 711 Medical Gases [] 704 Controlled Substances [] ENC Encapsulation [] SUS Suspension [] FER Fermentation/Tissue Culture [] TBL Tableting [] 705 Approved New Drugs [] LMX Liquid Mixing [] 706 Investigational New Drugs [] 707 Other (Specify) [] OTH Other (Specify) The Food and Drug Branch MUST BE NOTIFIED of any change in the above information as provided by California Health and Safety Code Section 26688. By signature, the applicant affirms that all information is true and correct. SIGNATURE OF APPLICANT:

PRINT NAME AND TITLE:

DATE:

EH-52 (01/2002)